

Claims

Sub B1

1. A vaccine composition comprising diphtheria (D), tetanus (T) and acellular pertussis (Pa) antigens and an adjuvant, wherein wherein the concentration of D per 5 0.5 ml dose of bulk vaccine does not exceed 5 Lf and is preferably 1-4 Lf, more preferably about 2 Lf; the concentration of T per 0.5 ml dose of bulk vaccine does not exceed 10 Lf and is preferably 2.5 - 7.5 Lf, more preferably about 5Lf and the Pa component comprises PT (pertussis toxoid), FHA (filamentous hemagglutinin) and pertactin (69K) wherein the concentration of PT per 0.5 ml dose of bulk vaccine does not exceed 10 ug and is preferably 2-10 ug, more preferably about 8ug; the concentration of FHA per 0.5 ml dose of bulk vaccine does not exceed 10 ug and is preferably 2-10 ug, more preferably about 8ug; and the concentration of 69K does not exceed 4 micrograms per 0.5 ml dose of bulk vaccine and is preferably in the range 10 0.5ug to 3 ug, more preferably 2 to 3ug, more preferably approximately 2.5ug per 0.5 15 ml dose of bulk vaccine.

2. A vaccine composition according to claim 1 having the composition: PT (8ug), FHA (8ug), 69K (2.5ug), D (2 Lf) and T (5 Lf) per 0.5 ml dose of bulk vaccine.

20 3. A vaccine composition according to ~~any one of claims 1 or 2~~ which additionally comprises one or more additional antigens.

4. A vaccine composition according to claim 3 wherein an additional antigen is hepatitis B surface antigen.

25 5. A vaccine composition according to claim 4 wherein the hepatitis B surface antigen is the S-antigen of HBsAg.

6. A vaccine composition according to claim 3 or claim 4 wherein an additional 30 antigen is present which provides immunity against one or more of Hib, polio or hepatitis A infection.

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7. A vaccine composition according to any previous claim wherein the adjuvant used in the formulation comprises aluminium hydroxide.

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8. A vaccine composition according to any previous claim wherein the adjuvant used in the formulation comprises aluminium phosphate.

9. A method of preventing disease in children or adolescent or adult subjects, which comprises vaccinating the subjects with a vaccine composition according to any one of claims 1 to 8.

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OPENING STATEMENT